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Dockets Management System
U.S. Department of Transportation
400 Seventh Street, S.W.
Washington, DC 20590-000 1

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Re: Docket No. RSPA 99-6213 (HM-218); Comments on notice of proposed rulemaking

Dear Sir or Madam:

These comments are offered on behalf of Andersen Products ("Andersen") of Haw River, North Carolina, in response to the notice of proposed rulemaking (NPRM) entitled **Hazardous Materials: Miscellaneous Amendments,** which was published in the *Federal Register* on September 30, 1999 (64 FR 53 166), under Docket No. RSPA 99-62 13 (HM-2 18). These comments are limited to the amendments proposed in the NPRM to the "small quantity exceptions" prescribed in § 173.4 of the Hazardous Materials Regulations (HMR).

Background, and interest of commentor.

Andersen is a manufacturer and distributor of sterilization systems used by hospitals, doctors and dentists to sterilize instruments and other articles used in medical treatment. Since an increasing number of devices used in such applications cannot be sterilized by steam, ethylene oxide (UN 1040, a gas designated as a material poisonous by inhalation (PM)[1]) is a preferred sterilizing

[1] Although ethylene oxide meets the criteria for a gas (i.e., normal boiling point below 20°C) its boiling point of 11°C is relatively close to the liquid "borderline" and it has a low vapor pressure (148 kPa at 20°C), compared to most gases. With regard to its identification in the HMR

(continued...)

agent, and the agent used in the systems manufactured by Andersen. The Andersen sterilization systems are the most widely-used systems for office-based sterilization applications, and the users of these systems have no alternative means of supply of the ethylene oxide necessary to operate the systems. As these systems are essential to the protection of human life, it is, therefore, critical that a means be available to readily supply the required sterilizing agents to the users of these systems.

The ethylene oxide used in Andersen's systems is supplied to the user in heat-sealed glass ampoules with maximum capacities of 20 ml. At present, Andersen ships these ampoules under the small quantity exceptions in § 173.4 of the HMR, under an approval issued by the Associate Administrator for Hazardous Materials Safety pursuant to the provisions of § 173.4(c). Andersen understands that DOT's rationale in issuing this approval was that, owing to the low vapor pressure and toxicity of ethylene oxide (see Footnote 1), the material could be safely transported under the provisions of § 173.4.[2] Since the amendments proposed in subject NPRM to §§ 173.4(a)(1)(i), (ii) and (iii) of the HMR would have the effect of reducing the quantity of PIH material (gas, as well as liquid) that may be contained in any inner packaging to 1 gram, Andersen is concerned with the effects of the amendment (if adopted) on its current approval, and, therefore, over Andersen's continuing ability to readily distribute and resupply critically-needed sterilizing agent in the 20 ml ampoules required in its sterilizing systems. Consequently, Andersen welcomes the opportunity to comment on the above-referenced NPRM.

Problem with proposed amendment. and suggested alternatives.

The NPRM proposes to amend §§ 173.4(a)(1)(i), (ii) and (iii) by replacing the words "Division 6.1, Packing Group I materials" with the words "materials poisonous by inhalation". As

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[1] (...continued)
as a Hazard Zone D PIH gas, it is noted that the inhalation toxicity of ethylene oxide is very near the 5,000 ppm one-hour LC_{50} (rat) upper "cut-off' value for classification as a Division 2.3 gas. In documents submitted to the UN Committee of Experts in 1992 by the United States, it was stated that in recently conducted tests employing modem inhalation testing protocols, a one-hour LC_{50} value for ethylene oxide of 4,439 ppm for female rats, and 5,748 ppm for male rats was determined. This suggests that the one-hour LC_{50} of ethylene oxide, when determined in a test using both male and female rats (as is provided for in the applicable test procedure prescribed in § 173.132(b)(3) of the HMR), may, indeed, be greater than the 5,000 ppm threshold for classification in Division 2.3. A liquid with this degree of inhalation toxicity would be assigned to Packing Group III.

[2] Indeed, prior to implementation several years ago of the revised classification criteria established under the Docket No. HM- 18 1 final rule, ethylene oxide was classified and transported as a flammable liquid, without subsidiary risk.

pertinent in the context of Andersen's concern, the effect of these changes is to extend the 1 gram inner packaging quantity limitation heretofore applying only to Division 6.1 Packing Group I materials (which, by definition, must be either liquids or solids), to also apply to PIH gases (to the extent that DOT may elect to approve transport of such gases pursuant to the provisions of § 173.4(c)). Note that Andersen's concern in this connection is not without basis, in that while § 173.4(c) permits the Associate Administrator to approve "Class 2" materials for transport in conformance with the requirements of "paragraphs (a)(1) through (a)(10) of this section", it does not provide the ability for the Associate Administrator to approve the transport of a such a material in inner packagings exceeding the limits prescribed in paragraph (a)(1) - limits which the NPRM seeks to revise.[3]

Since Class 2 materials (regardless of their division) may only be transported under the small quantity exceptions in § 173.4 when specifically approved by the Associate Administrator, there appears to be no compelling need to extend the applicability of any revised inner packaging quantity limitations (as may arise from the proposed amendment of §§ 173.4(a)(1)(i), (ii) and (iii)) to PIH gases, in that, if in approving any gas for transport under these small quantity exceptions the Associate Administrator determines that the "normal" 30 ml quantity limit is too high, a lower limit may be prescribed as a condition for the approval.[4] This being the case, Andersen respectfully requests that the proposed inner packaging quantity reduction not be made automatically applicable to any PIH gas (such as ethylene oxide) that may be approved pursuant to the provisions of § 173.4(c) (as would be the case if the proposed amendment were adopted), but, rather, that the effect of any reduction in the inner packaging quantity limit be specifically confined to PIH liquids.

RSPA's stated intent for the proposed amendment was to "clarify that the limit of one gram for Division 6.1 material per inner receptacle applies only to materials poisonous by inhalation" (see 64 FR 53168, emphasis added). From this it may be concluded that no significant substantive change was intended (i.e., the amendment was intended to be a "clarification"), and, consequently, that it was not intended that the amendment apply to materials other than the Division 6.1 materials

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[3] Consequently, it would appear that if the amendment is adopted as proposed, Andersen would be unable to continue to transport its 20 ml ampoules under the small quantity exceptions in § 173.4 without a DOT exemption permitting an increase in the inner packaging quantity.

[4] Note in this regard, that while § 173.4(c) does not clearly permit the Associate Administrator to approve an inner packaging quantity limit exceeding that prescribed in paragraph (a)(l), nothing prohibits the Associate Administrator from limiting the "normal" inner packaging quantity limit as a condition for approval of a material pursuant to the provisions of paragraph (c).

currently covered by the provision. Bearing this in mind, Andersen believes that its concerns can be resolved, while still achieving RSPA's stated intent, by revising §§173.4(a)(1)(i), (ii) and (iii) either by:

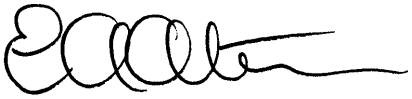
1) Removing the words "Division 6.1, Packing Group I materials" and adding in their place the words "liquid materials poisonous by inhalation"; or

1) Removing the words "Division 6.1, Packing Group I materials" and adding in their place the words "Division 6.1 materials poisonous by inhalation"

As previously stated, Andersen believes that under either of the alternative amendments suggested above, the Associate Administrator would continue to retain discretionary authority to limit the allowable inner packaging quantity for any PIH gas as a condition of the approval that would be required (pursuant to the provisions of § 173.4(c)) to authorize the carriage of such gas under the small quantity exceptions.

In conclusion, in light of the foregoing Andersen respectfully requests that §§ 173.4(a)(1)(i), (ii) and (iii) not be amended as proposed, but rather, to address the concerns outlined above while achieving RSPA's stated intent to clarify the provisions concerned, the paragraphs be amended as proposed herein. Andersen Products appreciates the opportunity to comment on these proposals, and please do not hesitate to contact me if you have questions, or need additional information, concerning these comments.

Sincerely,



E. A. Altemos

cc: Diane LaValle (DHM-11)
Bruce Fenn, Esq. (Andersen Products)